



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-21-21AT; Docket No. CDC-2021-0027]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Evaluation of Venous Thromboembolism Prevention Practices in U.S. Hospitals. This proposed study is designed to support a framework for improving hospital venous thromboembolism (VTE) prevention practices through the evaluation of current VTE prevention practices in U.S. adult general medical and surgical hospitals.

**DATES:** CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2021-0027 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each

proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Evaluation of Venous Thromboembolism Prevention Practices in U.S. Hospitals - New - National Center on Birth Defects and

Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is an important and growing public health problem. Each year in the U.S., it is estimated that VTE affects as many as 900,000 people, is responsible for up to 100,000 deaths, and is associated with healthcare costs of approximately \$10 billion. Recurrence after a VTE is common, and complications include post-thrombotic syndrome and chronic thromboembolic pulmonary hypertension. Over half of VTE events are associated with recent hospitalization or surgery and most occur after discharge. An analysis of the National Hospital Discharge Survey from 2007 to 2009 estimated that almost 550,000 U.S. adult hospitalizations had a discharge diagnosis of VTE each year. Hospital-associated VTE (HA-VTE) is often preventable but VTE prevention strategies are not applied uniformly or systematically across U.S. hospitals and healthcare systems.

The Agency for Healthcare Research and Quality (AHRQ) published a guide for preventing HA-VTE in 2016. The framework for improving VTE prevention in hospitalized patients includes a hospital VTE prevention policy, an interdisciplinary VTE team, standardization of VTE prevention processes, monitoring of processes and outcomes, and VTE prevention education for providers and patients. A VTE prevention protocol includes VTE

risk assessment, bleeding risk assessment (risk of bleeding with anticoagulant prophylaxis) and clinical decision support for appropriate prophylaxis (i.e., ambulation, anticoagulant prophylaxis, and/or mechanical prophylaxis) based on both VTE and bleeding risk assessments.

Despite evidence-based guidelines for VTE prophylaxis in at-risk hospitalized patients, there is systemic underuse of appropriate VTE prophylaxis. As many as 70% of HA-VTE events are potentially preventable but less than half of hospitalized patients receive appropriate VTE prophylaxis. An implementation gap exists between evidence-based guidelines for VTE prophylaxis in hospitalized adult patients and implementation of those guidelines in real-world hospital settings. The 2008 Surgeon General's Call to Action to Prevent DVT and PE included instituting formal systems related to risk assessment and the provision of prophylaxis to high-risk hospitalized patients. For World Thrombosis Day in 2016, the International Society on Thrombosis and Haemostasis (ISTH) issued a call to clinical leaders, hospitals, and payers to work together to make VTE risk assessment for all hospitalized patients a priority.

In England, The National Venous Thromboembolism Prevention Programme was launched in 2010 with the goal of reducing preventable HA-VTE morbidity and mortality (Roberts, 2017). VTE risk assessment was mandated for all adult patients on admission to an acute hospital utilizing a previously developed national VTE risk assessment tool/model. Hospitals were required to

report VTE risk assessment rates, with a financial incentive applied to achieve a target of 90%. This resulted in an impressive, sustained increase in VTE risk assessment rates with a corresponding increase in anticoagulant prophylaxis. There was evidence of significant reductions in HA-VTE and associated mortality following implementation of this program.

Unlike England, the U.S. has no national VTE prevention program with hospital risk assessment rates tied to financial incentives and no national VTE risk assessment tool/model. Various VTE risk assessment models (RAMs) have been developed and published to identify hospitalized patients whose risk for VTE is high enough to offset the risk of bleeding with anticoagulant prophylaxis. However, there is no standardized RAM currently in use across U.S. hospitals and healthcare systems. Implementation of risk assessment varies in terms of the patient population (e.g., medical vs. surgical), time frames (e.g., on admission, on transfer to another unit), method of administration (i.e., electronic vs. paper), person/s performing the risk assessment (e.g., physician, nurse, pharmacist), type of RAM (e.g., quantitative vs. qualitative), and linkage to a clinical decision support tool for appropriate VTE prophylaxis.

An evaluation of the extent to which U.S. hospitals utilize VTE risk assessment is needed to better understand the landscape around VTE prevention practices in real-world hospital settings in order to guide efforts and inform interventions to reduce the burden of HA-VTE. CDC is funding The Joint Commission to

evaluate VTE prevention practices in U.S. hospitals. The Joint Commission has had a role in patient safety through standards and performance measurement. It is the measure steward for two electronic clinical quality measures (eCQMs) on VTE prevention available for Center for Medicare and Medicaid Services Inpatient Quality Reporting and Joint Commission hospital accreditation since 2016. However, these two VTE prevention eCQMs only address the initiation of VTE prophylaxis within a specified timeframe; they do not assess the patient's level of VTE risk or the appropriateness of prophylaxis.

For this project, The Joint Commission, in collaboration with CDC, developed a survey on hospital VTE prevention practices. The survey was piloted in nine hospitals and their feedback was used to improve the survey. After OMB approval, the survey will be implemented by The Joint Commission as a one-time data collection in a nationally representative sample of U.S. adult general medical and surgical hospitals. No individual-level data will be collected. CDC will not receive any individual or hospital identifiable information.

The overall purpose of this project is to evaluate current VTE prevention practices in a nationally representative sample of U.S. hospitals (American Hospital Association adult general medical and surgical hospital service category) in order to support a framework for HA-VTE prevention. The information collected in this hospital survey will be used to improve understanding of hospital VTE prevention practices, which will

guide efforts and inform interventions to reduce the burden of HA-VTE. Specifically, the information collected on hospital VTE prevention policy and protocol, VTE prevention team, VTE data collection and reporting, VTE risk assessment, VTE prophylaxis safety considerations (i.e., bleeding risk assessment), ambulation protocol, VTE prevention education for providers and patients, and VTE prophylaxis monitoring and support will be used to assess the extent to which hospitals apply these components of the framework for HA-VTE prevention. The responses to specific VTE prevention practices can be used to assess VTE prevention practices by hospital characteristics (e.g., bed size, urban vs. rural location, teaching vs. non-teaching status) to better target efforts or interventions to improve HA-VTE prevention. Information collected on the barriers to establishing a hospital-wide VTE prevention policy will be helpful in addressing these challenges. Information will be collected on both adult general medical and surgical units since VTE prevention practices differ by specialty. Information on VTE risk assessment (e.g., who conducts the assessment, when is it performed, mandatory or optional, format, type of RAM) will improve understanding of real-world hospital VTE risk assessment practices. Information on the capacity of hospitals to collect data on VTE risk assessment will be helpful in determining the feasibility of VTE risk assessment as a VTE prevention performance measure. The data collected can also serve as a baseline for evaluation of future HA-VTE prevention initiatives.



Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
The Director of Patient Safety and Quality, the Chairperson of the Patient Safety Committee, other quality improvement professionals	Recruitment material: Implementation email and project information sheet	384	1	15/60	96
The Director of Patient Safety and Quality, the Chairperson of the Patient Safety Committee, other quality improvement professionals	Evaluation of Venous Thromboembolism Prevention Practices in U.S. Hospitals Questionnaire	384	1	1	384
					480

**Jeffrey M. Zirger,**

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